Comprehensive Risk Assessment for vCJD in France for Canadians and the Canadian Blood Supply

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DRAFT

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NOTE:

This most recent working draft of the comprehensive risk assessment has evolved from:

- the initial assessment of the "Impact of vCJD infection on Canadian Travellers to France and the UK," which has been revised in accordance with the recommendations of the International Expert Advisory Committee on vCJD (Toronto: March 17, 2000) to simplify the modeling approach.

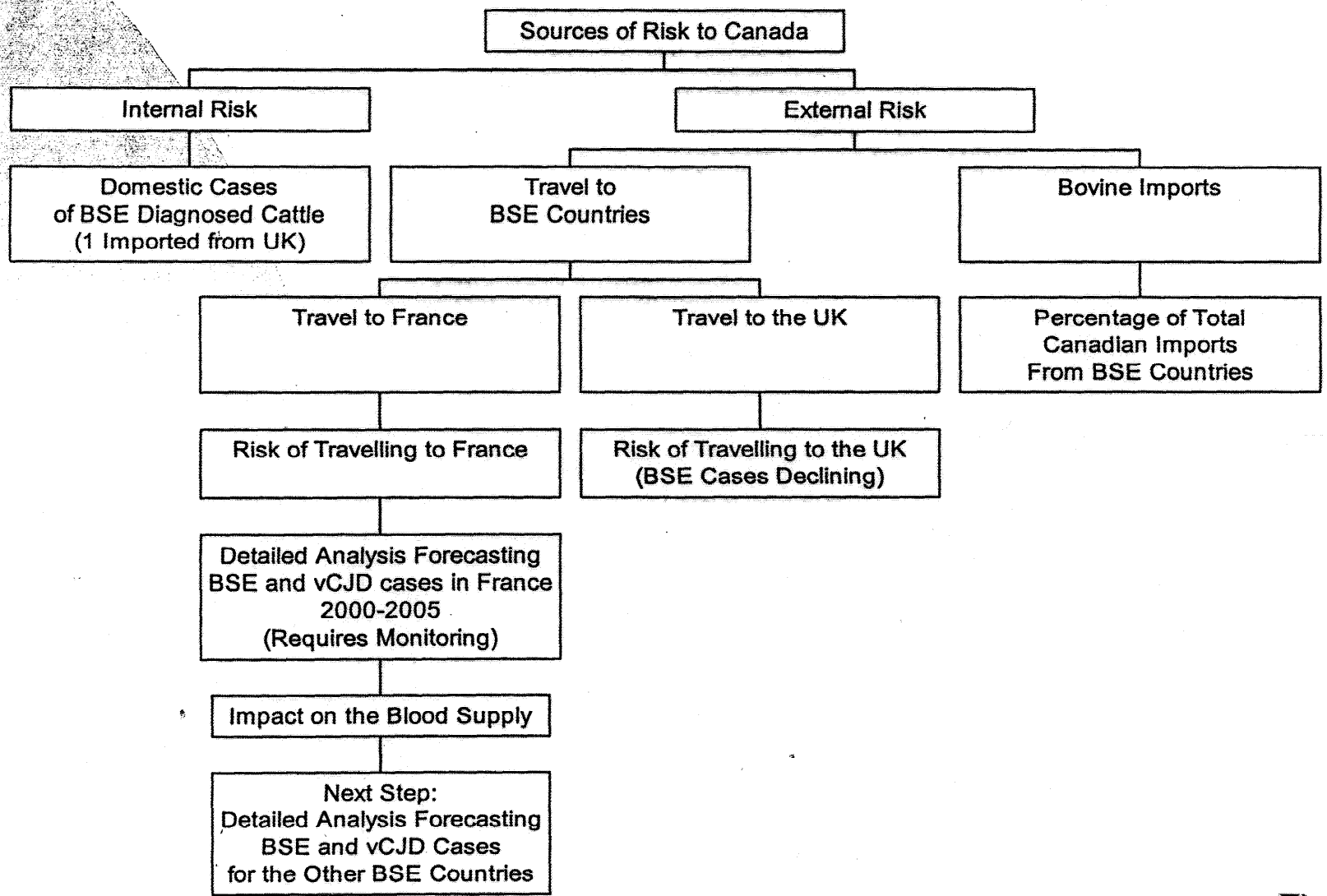
Introduction

- New variant Creutzfeldt-Jakob Disease (vCJD), first detected in the UK in 1996, is a neurodegenerative disease and is always fatal. Its incubation period is unknown. Health Canada has established a surveillance system should any cases of vCJD be identified.

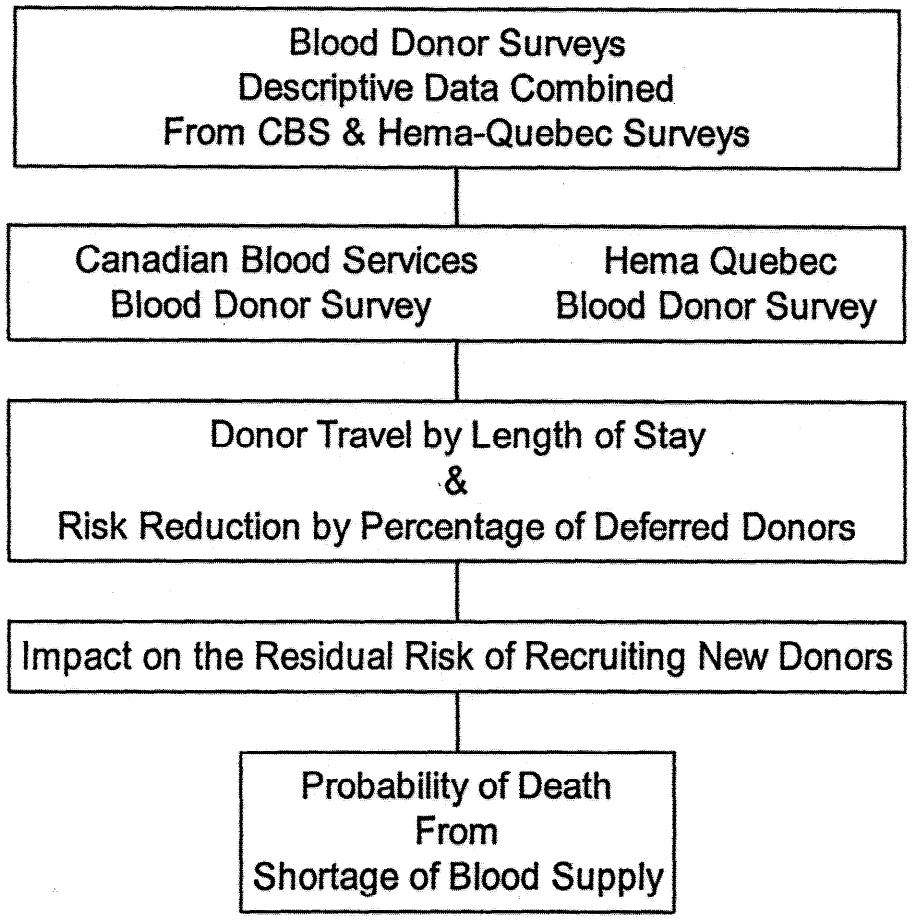
- There may be a theoretical risk of vCJD transmission through blood/blood products. As a result, the Health Canada policy defers any person who has spent six or more months in the UK (from 1980-1996) as a blood donor.

- Recently, sources in France have reported one probable vCJD case, in addition to two confirmed cases. Although the question is much broader from a Regulatory perspective, this analysis focuses on whether to extend the donor deferral policy to Canadian travellers to other countries.

Risk Assessment Overview: BSE and vCJD Risk to Canadians



Impact on the Blood Supply



Action Plan and Approach

- The Blood Borne Pathogens Division (BBPD) conducted a statistical analysis using Scenario Analysis and Monte Carlo Simulation.

- Factors considered include: number of vCJD cases in France and the UK, estimated number of slaughtered BSE infected cattle, and infectiousness of bovine tissue to humans.

- The analysis was performed using the available information and assuming various scenarios in order to estimate theoretical risks.

- As more biological or epidemiological data becomes available, a more complex framework may be designed. **This work demonstrates the extent of current uncertainty. Caution must be used in interpreting results.**

Available Information: UK and France

- Prions from cattle with Bovine Spongiform Encephalopathy (BSE) have infected humans and caused fatal neurodegeneration.

- It is estimated that 766,000 (C.I. 745,000 - 799,000) cattle infected with BSE were slaughtered for human consumption between 1980-1995, in the UK, and the infectiousness of bovine tissue to humans is 0.01(C.I. 0 - 1000).

- Age, sex, and population size is quite similar in France and the UK.

- Unlike the British, the French consume increased amounts of specified risk material (SRM) with bovine tissue suspected to be contaminated with BSE.

Available Information
United Kingdom

- Within the UK population of 60 million people, there are 52 confirmed cases of vCJD and 9 probable cases of vCJD.
- Approx. 700,000 Canadians visit the UK each year.
- Approx. 100% of beef consumed in the UK comes from UK cattle.
- As of April 1, 2000, the total number of cattle diagnosed with BSE is 179,128, and the total number of cattle is 11,339,000.

Available Information
France

- Within the French population of 60 million people, there are 2 confirmed cases of vCJD and 1 probable case of vCJD.
- Approx. 350,000 Canadians visit France each year.
- Approx. 10% of beef consumed in France comes from UK cattle.
- As of April 1, 2000 the total number of French cattle diagnosed with BSE is 80, and the total number of cattle is 20,214,000.

Unavailable Information

- The incubation period of vCJD is not known.
- The minimal dose and the effect of repeated, very low doses are not known.
- Age distribution of slaughtered, BSE infected cattle entering the human food chain is not known.
- Dietary habits in the UK and France among Canadian travellers.

Assumptions Used in the Risk Assessment Modelling

- The infective agent is assumed to infect all ages and both genders alike.
- The susceptibility of the British to the BSE infectious agent is similar to the susceptibility in France.

Assumptions Used in the Risk Assessment Modelling

- The travelling patterns and dietary characteristics remain constant over time.

- All travellers will consume at least 1 daily meal containing processed specified risk material (SRM). This may or may not result in infection.

- The exposure has been expressed as a ratio based on the total number of affected cattle in both countries and the import/export relationship between both countries. British exposure to contaminated SRM is 10 times higher than French exposure to contaminated SRM.

Table 1. Total Canadian Imports of Beef (kg) From Various Countries, 1988-2000

COUNTRIES	TOTAL IMPORTS	PERCENTAGE OF TOTAL CANADIAN IMPORTS	PERCENTAGE OF TOTAL CANADIAN BEEF CONSUMPTION
United Kingdom	226,992	0.02%	0.002%
France	85,158	0.01%	0.00076%
Switzerland	142	0.000001%	0.0000013%
Portugal	-	-	-
Belgium	28	0.0000003%	0.00000025%
United States of America	914,993,333	99.55%	8.19%
Netherlands	186,447	0.02%	0.0017%

TOTAL OF ALL CANADIAN IMPORTS OF BEEF (kg) FROM VARIOUS COUNTRIES, 1988-2000:	915,492,100

Results of the Modelling

Figure 1. The Probability of Acquiring the Disease (from BSE Infected Bovine) of a Canadian Travelling to the UK and France.

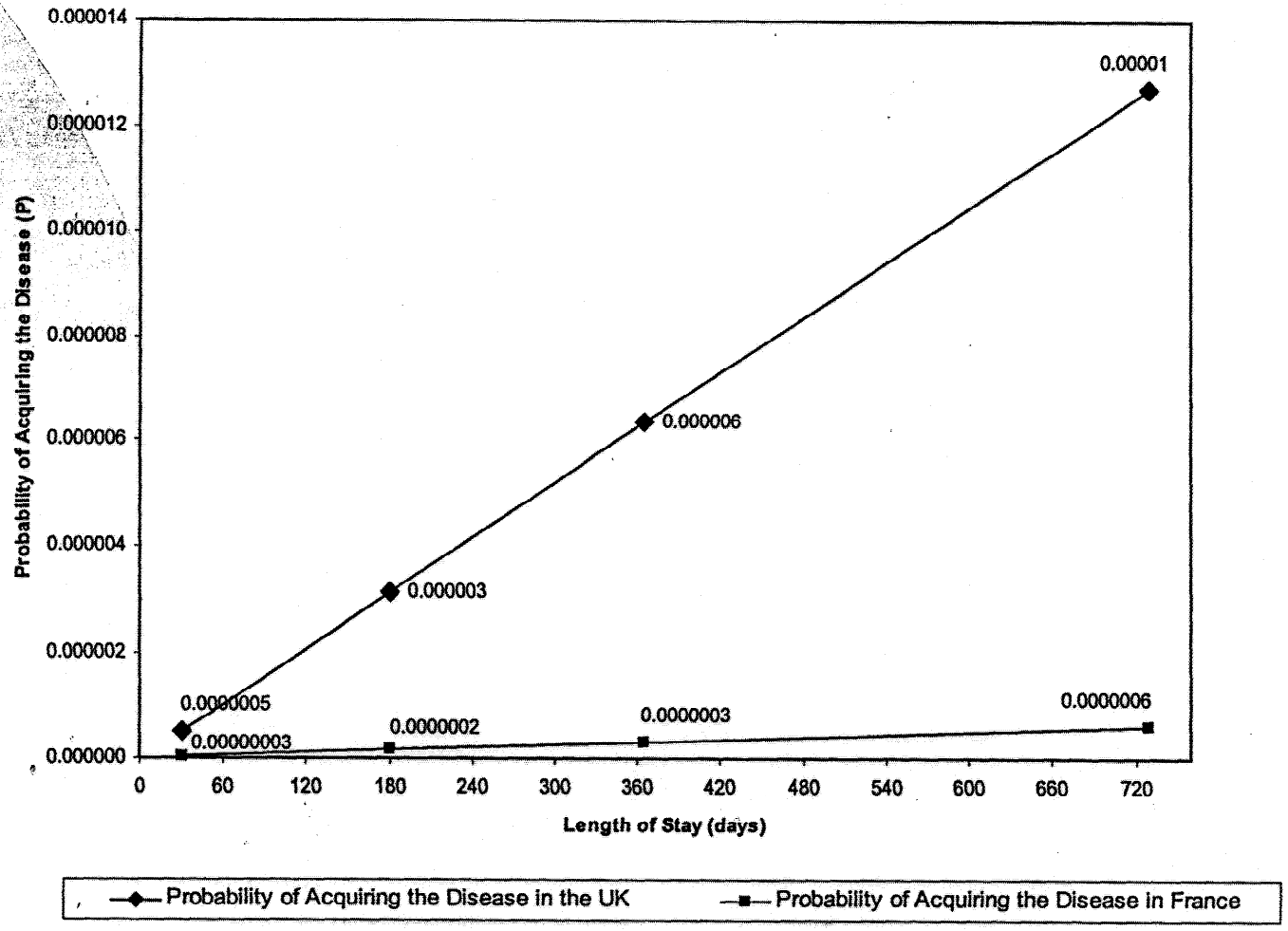


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Figure 1. - UK Probability Simulated Results

With 5th and 95th Percentiles

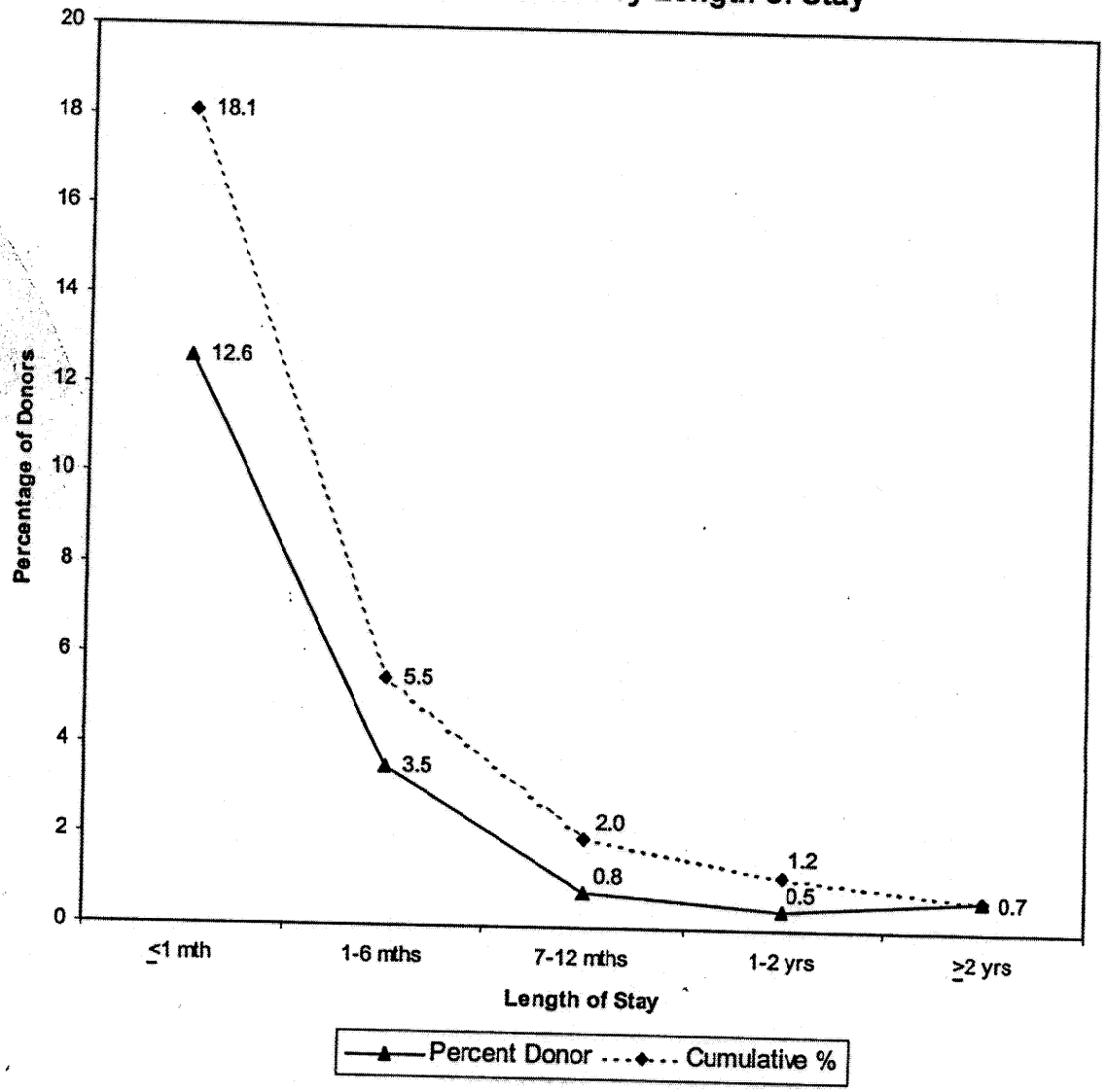
- A 1-month stay results in a probability of acquiring the disease of 5 in 10 million (0 - 0.0000005).
- A 6-month stay results in a probability of acquiring the disease of 3 in 1 million (0 - 000003).
- A 1-year stay results in a probability of acquiring the disease of 6 in 1 million (0 - 000006).
- A 2-year stay results in a probability of acquiring the disease of 1 in 100,000 (0 - 0.00001).

Figure 1. - French Probability Simulated Results

With 5th and 95th Percentiles

- A 1-month stay results in a probability of acquiring the disease of 3 in 100 million (0 - 0.00000003).
- A 6-month stay results in a probability of acquiring the disease of 2 in 10 million (0 - 0.0000002).
- A 1-year stay results in a probability of acquiring the disease of 3 in 10 million (0 - 0.0000003).
- A 2-year stay results in a probability of acquiring the disease of 6 in 10 million (0 - 0.0000006).

Travel History: Cumulative Percentage[1] of Surveyed Canadian Blood Donors[2] who Travel to the UK by Length of Stay



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Source: [1]Represents only Blood Donors who Travel

[2] Combined CBS and Hema-Quebec Blood Donor Survey Travel Data, Adjusted.

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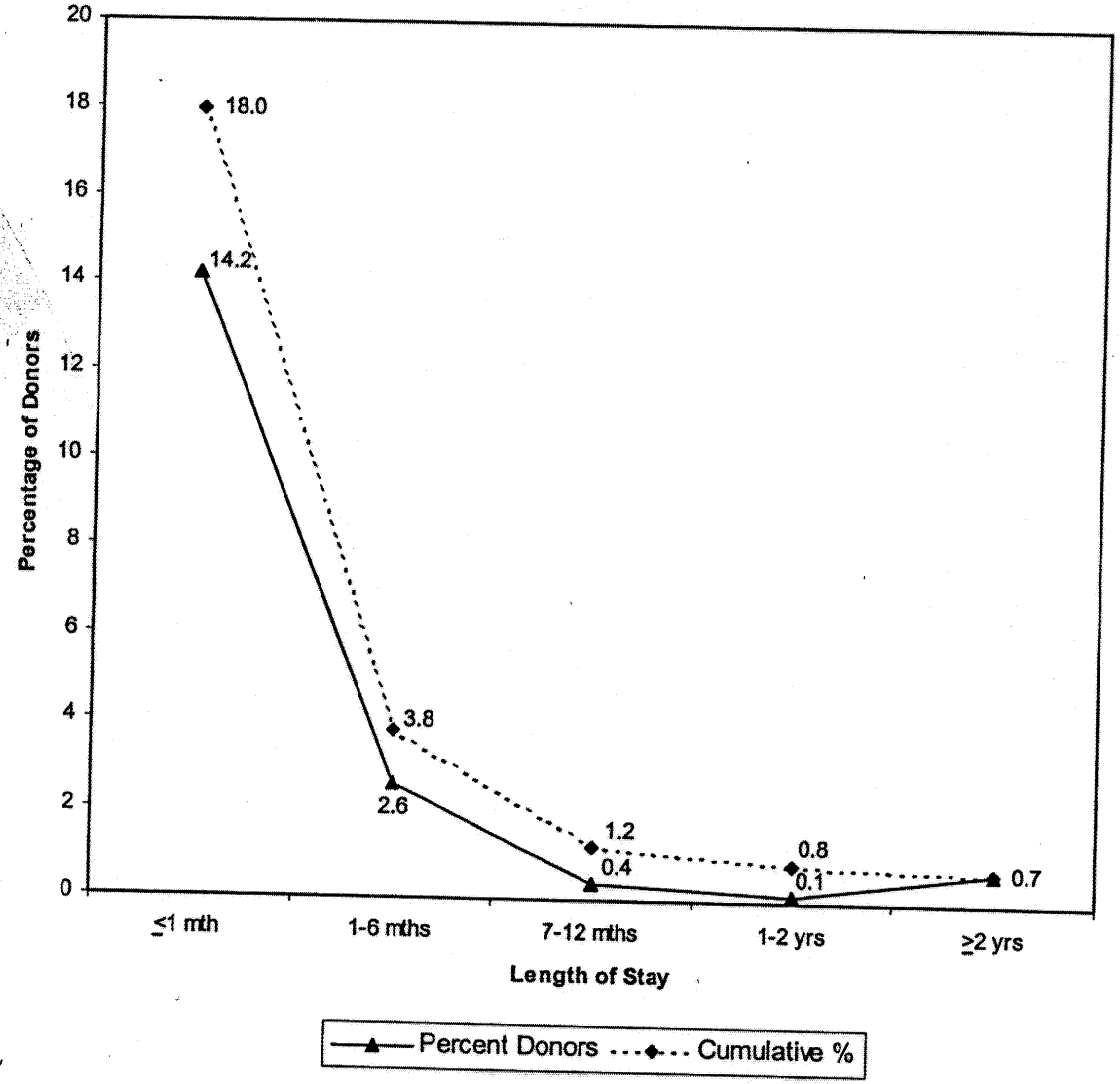
Travel History: Cumulative Percentage[1] of Surveyed Canadian Blood Donors[2] who Travel to France by Length of Stay



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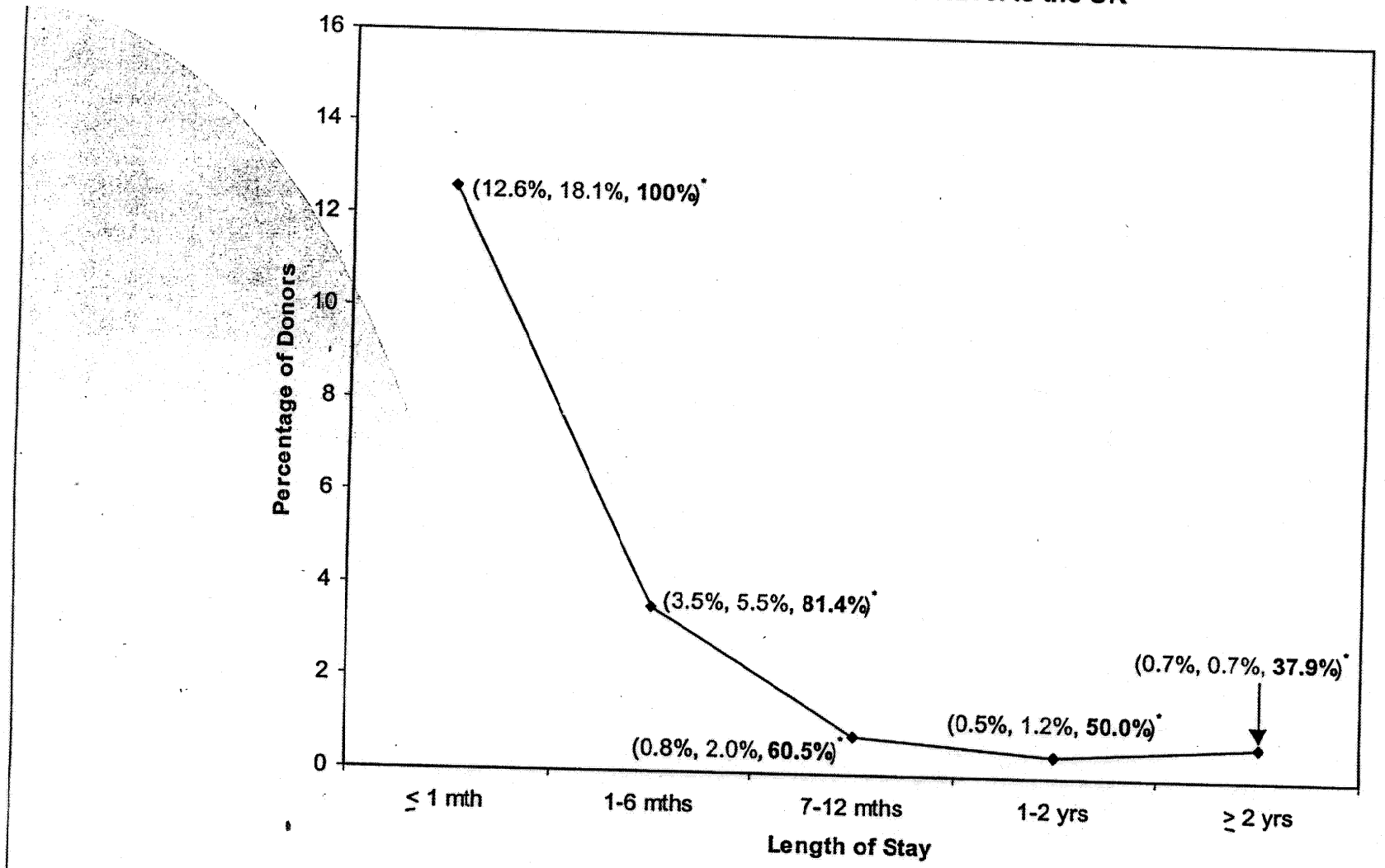
[2] Combined CBS and Hema-Quebec Blood Donor Survey Travel Data, Adjusted.

UK Based Risk: Percentage of Risk Reduction by Length of Stay in Surveyed Canadian Blood Donors who Travel to the UK



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*(Percent Donors, Cumulative Percent, **Risk Reduction**)

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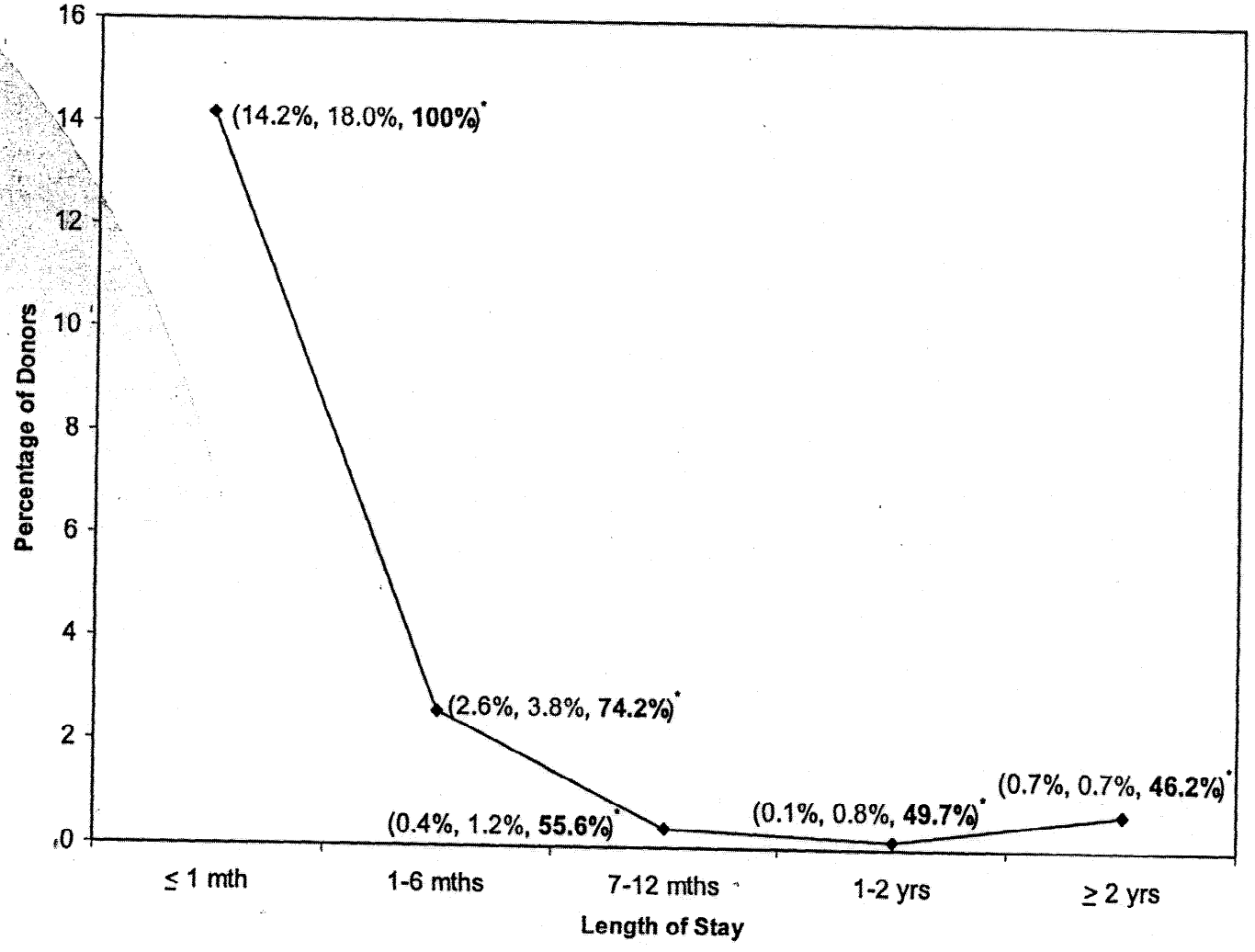
French Based Risk: Percentage of Risk Reduction by Length of Stay in Surveyed Canadian Blood Donors who Travel to France



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SUMMARY

Any decision has to take into account the relative risks and the true risk vs. the blood supply.